

### **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

#### **I. Status of the Claims**

Claims 1-22, 24-30, 32-34, 36, 38-41, 43 and 46-56 are currently pending in the application, with claims 1, 24-25, 32-33, 36 and 54-56 being the independent claims. Claims 37, 42 and 44-45 are canceled without prejudice to or disclaimer of the subject matter therein. Claims 23, 31 and 35 were previously canceled. Claims 1-22, 24-30, 32-34, 38 and 46-56 are withdrawn from consideration pursuant to a Restriction/Election requirement. Thus, claims 36, 39-41 and 43 are currently under consideration.

Claim 36 is amended to recite a method of treating major depression comprising administering a therapeutically effective amount of a pharmaceutical composition comprising an agonist of ATP-gated ion channel purinergic receptor P2X7 (P2X7R) activity to a subject suffering from major depression. Support for the amendment to claim 36 may be found throughout the specification, including paragraphs [0004]-[0005] at page 1, paragraph [0025] at page 3 and paragraph [0247] at pages 29-30 of the published patent application (Patent Application Publication No. US 2005/0147604 A1), claim 37 as previously presented and claim 42 as originally filed.

Claims 38-39 and 43 are amended to correct claim dependency.

These amendments do not introduce any new matter into the application and their entry is respectfully requested.

#### **II. The Personal Interview with the Examiners**

Applicants wish to thank Examiner Pak and Supervisory Examiner Nickol for the courtesy extended to Applicants' representative during the personal interview held on November 5, 2008. The amendments to the claims presented herein and the following remarks reflect the issues discussed and agreed upon during the personal interview.

### **III. The Rejection Under 35 U.S.C. § 102**

The Office Action, at pages 2-3, maintains the rejection of claims 36-37 and 39-43 as allegedly being anticipated by U.S. Patent No. 6,323,236 B2 to McElroy. Applicants respectfully traverse this ground of rejection.

#### **A. Summary of the Claimed Invention**

The presently claimed invention is directed to a method of treating *major depression* comprising administering a therapeutically effective amount of a pharmaceutical composition comprising an agonist of ATP-gated ion channel purinergic receptor P2X7 (P2X7R) activity to a subject suffering from major depression.

#### **B. McElroy Fails to Teach Each and Every Element of the Claimed Invention**

McElroy discloses methods for the treatment and prevention of *Impulse Control Disorders (ICDs)* by administering sulfamate derivatives such as topiramate. Mc Elroy fails to disclose or suggest an essential element of the claimed invention.

McElroy fails to disclose or suggest a method of treatment of *major depression*. Applicants submit that Impulse Control Disorders (ICDs) and depression are separate and distinct disorders that are characterized by different symptoms and behavior. The different status of ICDs is clearly stated in McElroy, which teaches that Impulse Control Disorders are listed in a residual category, "Not Elsewhere Classified", that includes intermittent explosive disorder (ED), kleptomania, pathological gambling, pyromania, trichotillomania, and ICDs Not otherwise specified (NOS), such as compulsive buying or shopping, repetitive self-mutilation, non-paraphilic sexual addictions, severe nail biting, compulsive skin picking, personality disorders with impulsive features, attention deficit/hyperactivity disorder, eating disorders characterized by binge eating, and substance use disorders (*see* column 1, lines 39-67). Contrary to the Office's allegation, that "McElroy teach a method of administering tenidap for treatment of major depression" (*see* page 2 of the Office Action), nowhere does Mc Elroy include major depression among ICDs or disclose a method of treating major depression.

Applicants have previously stated (*see* Amendment and Reply filed on April 3, 2008), that ICDs and major depression are distinct medical indications, as evidenced by their different classification in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR), published by the American Psychiatric Association (*see* also McElroy at col. 1, lines 49-67).

In further support to the evidence that ICDs and major depression are different disorders, Applicants submit herewith the declarations of two experts in the field of psychiatry: Professor Dr. Norbert Müller, Head of the Psychoneuroimmunology Research Group at the Psychiatry and Psychotherapy Hospital of the University of Munich, and Dr. Florian Holsboer, Director of the Max Planck Institute of Psychiatry in Munich.

These declarations provide clear evidence that ICDs and major depression are different medical indications, which are characterized by different symptoms and different classification, and are assessed and diagnosed using different assessment scales.

Accordingly, at least for the reasons stated above, McElroy fails to anticipate the claimed invention and the rejection is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

### CONCLUSION

All of the stated grounds of rejection have been properly traversed or rendered moot. Thus, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date December 2, 2008

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